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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,795	05/28/2004	Michael A. Slivka	101896-252 (DEP5319)	3794

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EXAMINER

ARAJ, MICHAEL J

ART UNIT	PAPER NUMBER
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3775

NOTIFICATION DATE	DELIVERY MODE
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02/08/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No. 10/709,795	Applicant(s) SLIVKA ET AL.	
	Examiner MICHAEL J. ARAJ	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10-19, 21-27, 29-33 and 35 is/are pending in the application.
- 4a) Of the above claim(s) 2-5, 13-16 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6, 7, 10-12, 17-19, 21-24, 26, 27, 29-33 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/16/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 recites the limitation "the cavity" in lines 5-6. There is insufficient antecedent basis for this limitation in the claim.

Claim 36 recites the limitation "the recess" in line 6. There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 17-19, 21-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment made to claim 12, "the distal portion of the cavity" leaves the claim unclear. The claim describes that the head of the bone-engaging member is seated in 'a distal portion of the cavity'. The claim then further describes that the spinal fixation element extends into the distal

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portion of the cavity but prevents contact between the bone-engaging member and the spinal fixation element. This appears to be unclear. If the spinal fixation element is occupying the same distal portion to which the bone-engaging portion is, then contact would be made by these two elements. This would contradict what is believed to be said in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 6, 7, 10-12, 17-19, 21, 22-24, 26, 27, 29-33 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker (US Patent Application Publication 2004/0260284) in view of Biedermann et al (US Patent Application Publication 2004/0049190) and further in view of Schl pfer (US Patent 6,063,090)

Parker discloses (**Figure 1**) a device comprising: a bone-engaging member (**105**) having a spherical head (**110**) formed thereon; a U-shaped receiver member (**115**); the receiver (**115**) having a proximal recess/seat (**155**) that receives a (rigid or flexible since it has to be one) spinal rod (**200**); a threaded (**150**) setscrew/fastener (**145**) to mate with the receiver to lock the spinal rod in position while allowing free polyaxial movement of the bone-engaging member (**105**); the bone-engaging member (**105**) has its head mated to a distal cavity (**112**) of the receiver.

Parker fails to disclose an opening extending between the proximal recess (**155**) and distal cavity (**112**) where the opening is sized to prevent passage of a spinal fixation element as well as the opening having a size that allows a portion of the spinal fixation element to extend into the distal cavity.

Biedermann et al teach (**Figures 3 and 4; Page 2, Paragraph 0027; and Page 3, Paragraph 0034**) that a passageway (**17**) too small to allow the spinal rod to pass is provided to allow a screw driver to engage the bone-engaging member. This allows the bone-engaging member to be pre-assembled to the U-shaped receiver member and ready to accept the spinal rod immediately after fixation in the bone without any intermediate steps thereby minimizing the complexity and duration of surgery. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide for a small passageway between the proximal recess and distal cavity of Parker in order to allow for the components to be pre-assembled thereby reducing surgical complexity and duration.

Schläpfer teaches (**Figures 7 and 9**) an arrangement such that the spinal rod (**1**) is partially seated within the distal cavity which houses a flat-topped (**9**) polyaxial screw (**2**). It would have been obvious to one having ordinary skill in the art at the time of invention to substitute the hole design of Schläpfer which allows the spinal rod to partially extend into the distal cavity and to substitute a fully-round headed polyaxial screw with a flat-topped polyaxial screw in order to provide an equivalent means of supporting a spinal rod on a polyaxial screw with predictable results.

The combination of Parker, Biedermann et al and Schläpfer disclose and teach all of the claimed limitations except for the spinal fixation element being formed from a material from the group consisting of stainless steel, titanium, non-absorbable polymers, absorbable polymers, and combinations thereof.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to select a material from applicant's group of appropriate materials since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

Applicant's arguments filed on March 30, 2009 have been fully considered but they are not persuasive. Applicant argues that Parker does not reasonably suggest a non-locking polyaxial bone screw. The applicant cites paragraph [0004] to show that Parker locks the screw with respect to the receiver. This is only stated in the Description of the Related Art and is not further disclosed in the Detailed Description of the Invention. Parker only specifically discloses the locking member being inserted into the receiver which keeps the rod in place with respect to the receiver. Parker is silent to the screw being locked in combination with the rod and the receiver. Furthermore, it appears that the screw is still movable with respect to the receiver with respect to looking at Figure 1.

Applicant also states that Parker further reasonable suggests that the pedicle screw includes an insert because the device would not be enabled without one. Parker discloses the possibility of an insert "floating saddle" but does not require one to function as intended.

Applicant also argues the obviousness of combining Parker, Biedermann and Schlapfer. The inclusion of Schlapfer to modify the combination of Parker and Biederman to have a hole shaped like the hole in the receiver member of Schlapfer as depicted in Figures 7 and 9 as well as substituting the flat-topped screw of Schlapfer for the round screw of Parker is obvious. All that was gleaned from the Schlapfer reference was that an arrangement of a hole located within a receiver which on its top receives a spinal rod situated slightly within the space of a polyaxial screw can rotate. One would reasonably substitute one design for the other with predictable results in order to provide for a rod receiving structure.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J. ARAJ whose telephone number is (571)272-5963. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael J Araj/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art Unit 3775